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EXAMINER

ODLAND, KATHRYN P

ART UNIT	PAPER NUMBER
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3743

DATE MAILED: 01/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/782,534

Applicant(s)

CRAGG ET AL.

Examiner

Kathryn Odland

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 November 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-52 is/are pending in the application.
- 4a) Of the above claim(s) 7, 12-14, 18, 20, 22, 25, 28-44 and 50-52 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8-11, 15-17, 19, 21, 23, 24, 26, 27 and 45-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4, 5, 12-17. 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Species 2 (Figure 18) in Paper No. 20 is acknowledged.
2. Claims 7, 12-14, **18, 20**, 22, 25, **28-44**, and 50-52 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Species, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 20.

Information Disclosure Statement

The MPEP states the following with respect to large information disclosure statements:

*Although a concise explanation of the relevance of information is not required for English language information, applicants are encouraged to provide a concise explanation of why the English-language information is being submitted. Concise explanations (especially those that point out the relevant pages and lines) are helpful to the Office, particularly where documents are lengthy and complex and applicant is aware of a **section that is highly relevant to patentability** or where a large number of documents are submitted and **applicant is aware that one or more is highly relevant to patentability**. -- M.P.E.P. § 609 (emphasis added).*

"Aids to Compliance With Duty of Disclosure," item 13:

*It is desirable to avoid the submission of long lists of documents if it can be avoided. Eliminate clearly irrelevant information and marginally pertinent cumulative information. If a long list is submitted, **highlight those documents which have been specifically brought to Applicant's attention and/or are known to be of the most significance**. -- M.P.E.P. § 2004 (emphasis added).*

Therefore, it is recommended that if any information that has been cited by Applicant in the Information Disclosure Statement(s) is known to be material to patentability as

defined by 37 C.F.R. § 1.56, Applicant should present a concise statement as to the relevance of that/those particular documents.

Further, the IDS submissions in Paper No. 8-11 have not been considered since the copy of the references was not present in the file. If these IDS submissions are to be considered a copy of the references along with a statement of relevance for each reference cited is requested.

Specification

3. The disclosure is objected to because of the following informalities: on page 2 in the cross-reference information, the date missing is required.

Appropriate correction is required.

Claim Rejections - 35 USC § 102/103

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-6,8-11,15-17,19,21,23,24,26,27 and 45-49 are rejected under 35 U.S.C. 102(e)/103(a) as being anticipated by Reiley et al. in US Patent No. 6,440,138.

Regarding claim 1, Reiley et al. disclose a discectomy apparatus for performing a discectomy of an intact or damaged intervertebral spinal disc, the intervertebral spinal disc having a disc body formed of a nucleus and annulus the apparatus having an elongated discectomy instrument (such as 22, 110, etc. and their respective associated components) having a discectomy instrument body extending between a discectomy instrument proximal end and instrument distal end, a cutting head (such as 22, 110, etc.) located in a distal portion of the discectomy instrument, the instrument body and cutting head dimensioned to fit within and to extend through the axial bore, and means (such as via expansion and bending) for extending the cutting head laterally away from the axial disc opening toward or through the annulus of the intervertebral spinal disc; and operating means (such as 56) coupled to the instrument body proximal end for operating the cutting head to form a disc cavity within the annulus, the disc cavity extending laterally and away from the disc opening within the annulus, or to form a disc space by further extension of the disc cavity through at least a portion of the annulus, as recited in columns 3-7 and seen in figures 3-29. Regarding the phrase, *"through a trans-sacral axial bore extending cephalad and axially from a sacral position of a sacral vertebral body through one or more vertebral body and through a vertebral body endplate and axial disc opening into the nucleus of the intervertebral spinal disc"* functional language does not hold patentable weight in an apparatus claim. Thus, given the structure of Reiley et al. the device is capable of performing in a bore made in any orientation.

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Regarding claim 2, Reiley et al. disclose that as applied to claim 1, as well as, aspiration means for aspirating the disc cavity or disc space, as recited in column 7, lines 10-25, for example.

Regarding claim 3, Reiley et al. disclose that as applied to claim 1, as well as, a cutting head having a fragmenting element for fragmenting the nucleus or annulus into fragments when operated by the operating means, as recited in columns, 1-7.

Regarding claim 4, Reiley et al. disclose that as applied to claim 3, as well as aspiration means for aspirating nucleus or annulus fragments from the disc cavity or disc space, as recited in column 7, lines 10-25, for example.

Regarding claim 5, Reiley et al. disclose that as applied to claim 3, as well as, irrigation means for delivering irrigation fluid into the disc cavity or disc space; and aspiration means for aspirating the nucleus fragments and irrigation fluid from the disc cavity or disc space, as recited in column 7, lines 10-25, for example.

Regarding claim 6, Reiley et al. disclose that as applied to claim 3, as well as, operating means further having axially rotating means (such as 142, 108, etc. and associated components) coupled to the discectomy instrument proximal end for rotating the laterally directed fragmenting element at least partially around the disc opening to sweep through the nucleus to fragment at least a portion of the nucleus to form a disc

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cavity extending laterally away from the axial disc opening and toward the annulus or to fragment a portion of the annulus to form a disc space extending away from the axial disc opening, as recited in columns 1-7, for example.

Regarding claim 8, Reiley et al. disclose that as applied to claim 6, as well as, a fragmenting element having at least one cutting wire (such as 22, 140, etc.) element attached to the distal end of the discectomy instrument body that is confined during introduction of the discectomy instrument through the axial bore and that extends radially outward at **about** 90.degrees from the distal end of the discectomy instrument body and into the nucleus when passed through the axial disc opening and rotated, whereby the rotation of the cutting wire element through the nucleus fragments or compresses the nucleus, as seen in figures 3, 11, etc.

Regarding claims 9, 11, and 19, Reiley et al. disclose that as applied to claims 8, 10 and 16, as well as, a cutting wire element having a weighted cutting wire element free end, wherein all wire will have some weight component. The specification of the current application does establish the degree to which the element is weighted.

Regarding claim 10, Reiley et al. disclose that as applied to claim 6, as well as, a fragmenting element having at least two cutting elements (such as multiple brushes/bristles) attached to the distal end of the discectomy instrument body that are confined during introduction of the discectomy instrument through the axial bore and

that extend radially outward at about 90.degrees from opposed sides of the distal end of the discectomy instrument body and into the nucleus when passed through the disc opening and rotated, whereby the rotation of the cutting wire elements through the nucleus fragments or compresses the nucleus, as recited in columns 1-7 and seen in figures 9-11, for example.

Regarding claim 15, Reiley et al. disclose that as applied to claim 1, as well as, laterally extending means further having a deflection catheter (such as 12, etc.) having a deflection catheter lumen extending between a deflection catheter proximal and a deflection catheter distal end, wherein a distal portion of the deflection catheter is angled with respect to a proximal portion of the deflection catheter to orient the deflection catheter lumen distal end opening at about 90.degrees with respect to the deflection catheter lumen in the proximal portion of the deflection catheter and the discectomy instrument body and cutting head are extended through the deflection catheter, wherein given the structure, it is capable of axial movement as well as bending given its structure, as stated in column 4.

Regarding claim 16, Reiley et al. disclose that as applied to claim 15, as well as, a discectomy instrument body further having a discectomy instrument shaft extending through the deflection catheter (such as 12, etc.) lumen having a discectomy instrument shaft proximal end and a discectomy instrument shaft distal end; and the cutting head has at least one fragmenting element (such as 22) attached to the discectomy

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instrument shaft distal end that is confined within the deflection catheter lumen during introduction (as recited in column 4) of the discectomy instrument through the axial bore and that is extendable radially outward at *about* 90 degrees from the distal end of the discectomy instrument body and into the nucleus when extended from the deflection catheter lumen distal end opening (given the structure it is capable of axial as well as bending motions); and the operating means (30) having means coupled with said discectomy instrument shaft proximal end for selectively extending said fragmenting element out of said deflection catheter lumen end opening and laterally into the nucleus and toward the annulus; and deflection catheter rotating means (56) coupled to the deflection catheter proximal end for sweeping the laterally directed fragmenting element at least partially around the disc opening to sweep through the nucleus to fragment at least a portion of the nucleus to form the disc cavity or disc space, as recited in columns 4-7 and seen in figure 3 for example.

Regarding claim 17, Reiley et al. disclose that as applied to claim 16, as well as, a cutting head having a cutting wire element (22).

Regarding claim 18, it does not appear that claim 18 is drawn to the species elected. Thus, it has not been examined.

Regarding claim 20, it does not appear that claim 20 is drawn to the species elected. Thus, it has not been examined.

Regarding claim 21, Reiley et al. disclose that as applied to claim 15, as well as, a tubular discectomy instrument shaft extending through the deflection catheter lumen, the discectomy instrument shaft having a shaft lumen extending between a discectomy instrument shaft proximal end and a discectomy instrument shaft distal end, the discectomy instrument shaft having a cutting tool deploying side opening; the cutting head (such as 22) having at least one fragmenting element fitted within the discectomy instrument shaft lumen that is retracted into alignment (as recited in column 4) with the discectomy instrument shaft and is confined within the deflection catheter lumen during introduction of the discectomy instrument through the axial bore and that is extendable outward from the side opening and into the nucleus; and the operating means further having means (such as 30) for selectively extending the fragmenting element out of the side opening and away from discectomy instrument shaft; and deflection catheter rotating means (such as 56) coupled to the deflection catheter proximal end for sweeping the fragmenting element at least partially around the disc opening to sweep through the nucleus to fragment at least a portion of the nucleus to form the disc cavity or disc space, as recited in columns 2-7 and seen in figures 1-28.

Regarding claim 23, Reiley et al. disclose that as applied to claim 1, as well as, a discectomy instrument body further having a tubular discectomy instrument shaft extending through the deflection catheter lumen, the discectomy instrument shaft having a shaft lumen extending between a discectomy instrument shaft proximal end and a

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discectomy instrument shaft distal end, the discectomy instrument shaft having a cutting tool deploying opening; and a drive shaft (such as 30) having a drive shaft body fitted within said shaft lumen and extending between a drive shaft proximal end extending proximally from said shaft proximal end and a drive shaft distal end extending distally from said shaft distal end; the laterally extending means for deflecting said discectomy instrument shaft and said drive shaft through the disc opening to orient the fragmenting element transversely with respect to the axial bore; the cutting head (22) having a fragmenting element mounted to said drive shaft distal end, whereby the fragmenting element is laterally oriented toward the annulus of the spinal disc when extended from the axial bore through the axial disc opening; and the operating means (such as 56) further having means for rotating said drive shaft to rotate said fragmenting element with respect to said instrument shaft to fragment the nucleus; and instrument shaft rotating means coupled to the instrument shaft proximal end for sweeping the laterally directed fragmenting element at least partially around the disc opening to sweep through the nucleus to form the disc cavity or disc space, as recited in columns 2-7.

Regarding claim 24, Reiley et al. disclose that as applied to claim 23, as well as, deflecting means having a deflection catheter having a deflection catheter lumen extending between a deflection catheter proximal and a deflection catheter distal end, wherein a distal portion of the deflection catheter is (*capable of being*) angled with respect to a proximal portion of the deflection catheter to orient the deflection catheter lumen distal end opening at *about* 90.degrees with respect to the deflection catheter

lumen in the proximal portion of the deflection catheter and forms the means for extending the cutting head laterally; and the discectomy instrument shaft, the drive shaft, and fragmenting element are fitted within the deflection catheter lumen, as recited in columns 2-7.

Regarding claim 26, Reiley et al. disclose that as applied to claim 1, as well as, a discectomy instrument body further having a tubular discectomy instrument shaft extending through the deflection catheter lumen, the discectomy instrument shaft having a fluid delivery shaft lumen extending between a discectomy instrument shaft proximal end and a discectomy instrument shaft distal end, the discectomy instrument shaft having a distal fluid delivery head having at least one fluid delivery port from said fluid delivery lumen; the laterally extending means comprises means for deflecting said discectomy instrument shaft and said drive shaft through the disc opening to orient the distal fluid delivery head laterally toward the annulus of the spinal disc when extended from the axial bore through the axial disc opening; and the operating means further comprises: means for applying fluid under pressure through said fluid delivery lumen and from the fluid delivery port as a fluid jet having a force sufficient to lyse the nucleus or annulus; and instrument shaft rotating means (such as 56) coupled to the instrument shaft proximal end for sweeping the laterally directed fluid delivery head and port at least partially around the disc opening to sweep through and lyse the nucleus or annulus to form the disc cavity or disc space, as recited in column 2-7, with emphasis

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on column 7, lines 10-28, where functional language does not hold patentable weight in apparatus claim. Further the apparatus is capable of performing as claimed.

Regarding claim 27, Reiley et al. disclose that as applied to claim 26, as well as, deflecting means having a deflection catheter having a deflection catheter lumen extending between a deflection catheter proximal and a deflection catheter distal end, wherein a distal portion of the deflection catheter is *(capable of being)* angled with respect to a proximal portion of the deflection catheter to orient the deflection catheter lumen distal end opening at **about** 90.degrees with respect to the deflection catheter lumen in the proximal portion of the deflection catheter and forms the means for extending the cutting head laterally; and the discectomy instrument shaft, drive shaft, and fragmenting element are fitted within the deflection catheter lumen, as recited in columns 2-7.

Regarding claims 39-43, it does not appear that these claims are directed to the species elected. Thus, they have not been examined.

Regarding claim 45, Reiley et al. disclose that as applied to claim 1, as well as, an elongated discectomy sheath (such as 34) having a sheath lumen extending between a sheath proximal end and a sheath distal end and having a sheath body length sufficient to extend from a skin incision *through the trans-sacral axial bore to locate the sheath distal end at the disc opening, whereby the discectomy instrument is introduced to the*

axial disc opening through the sheath lumen, as recited in column 4. Further, functional language does not hold patentable weight in an apparatus claim. Further, the apparatus of Reiley et al. is capable of performing the function.

Regarding claim 46, Reiley et al. disclose that as applied to claim 1, as well as, an elongated discectomy sheath (such as 34) having a sheath lumen extending between a sheath proximal end and a sheath distal end and having a sheath body length sufficient to extend from a skin incision through the trans-sacral axial bore to locate the sheath distal end at the disc opening, whereby the discectomy instrument is introduced to the axial disc opening through the sheath lumen; and aspiration means for aspirating nucleus or annulus fragments from the disc cavity or disc space means through the sheath lumen, as recited in column 4 and column 7. Further, functional language does not hold patentable weight in an apparatus claim. Further, the apparatus of Reiley et al. is capable of performing the function.

Regarding claim 47, Reiley et al. disclose that as applied to claim 1, as well as, an elongated discectomy sheath (such as 34) having a sheath lumen extending between a sheath proximal end and a sheath distal end and having a sheath body length sufficient to extend from a skin incision through the trans-sacral axial bore to locate the sheath distal end at the disc opening, whereby the discectomy instrument is introduced to the axial disc opening through the sheath lumen; irrigation means for delivering irrigation fluid into the disc cavity or disc space; and aspiration means for aspirating nucleus or

annulus fragments from the disc cavity or disc space means through the sheath lumen, as recited in column 4 and column 7. Further, functional language does not hold patentable weight in an apparatus claim. Further, the apparatus of Reiley et al. is capable of performing the function.

Regarding claim 48, Reiley et al. disclose that as applied to claim 1, as well as, means for accessing (via 34 and 12) a sacral position of a sacral vertebral body; and means operable from the accessed sacral position for boring a trans-sacral axial bore cephalad and axially through the vertebral bodies of a series of adjacent vertebral bodies and any intervertebral, spinal discs and into or through the selected spinal disc providing at least a caudal axial disc opening into the nucleus of the selected spinal disc, as recited in columns 2-7. Further, functional language does not hold patentable weight in an apparatus claim. Further, the apparatus of Reiley et al. is capable of performing the function.

Regarding claim 49, Reiley et al. disclose that as applied to claim 1, as well as, means for accessing an anterior sacral position of a sacral vertebral body (via 34 and 12); and means operable from the accessed anterior sacral position for boring a transsacral axial bore cephalad and axially through the vertebral bodies of a series of adjacent vertebral bodies and any intervertebral, spinal discs and into or through the selected spinal disc providing at least a caudal axial disc opening into the nucleus of the selected spinal disc, as recited in columns 2-7. Further, functional language does not hold patentable

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weight in an apparatus claim. Further, the apparatus of Reiley et al. is capable of performing the function.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathryn Odland whose telephone number is (703) 306-3454. The examiner can normally be reached on M-F (7:30-5:00) First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A Bennett can be reached on (703) 308-0101. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9302.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1113.

KO



Henry A Bennett
Supervisory Patent Examiner
Group 3700